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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,791	11/20/2003	Kevin R. Seifert	P-20152.00	8594

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EXAMINER	
SMITH, STEPHANIE R	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,791	SEIFERT ET AL.	
	Examiner	Art Unit	
	Stephanie Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7 April 2004*. July 29, 2004, April 8, 2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDSs) submitted on April 7, 2004, July 29, 2004, and April 8, 2005 were filed after the mailing date of the application on November 20, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7, 9-20, and 22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Heil et al (WO 99/53993). Referring to claims 1, 22, and 27, Heil et al. teach an implantable defibrillation lead for the right ventricle that contains a fixation element, a defibrillation electrode, and a sensor (see page 3, lines 26-33; page 4, lines 3-7; and figures 5 and 12). With reference to claims 2 and 25, a portion of the defibrillation electrode is placed along the septal wall of the right ventricle when the fixation element is coupled to the endocardial surface in proximity to the right ventricular apex (see figures 5 and 12). Regarding claim 3, the distal tip contains a pacing/sensing electrode that can be positioned from the distal end of the defibrillation electrode by a distance of preferably 1-3 centimeters (see page 8, lines 14-17). The lower end of this

range falls within the upper limit of the range taught by the Applicant. With regards to claims 4 and 28, Heil et al. also teach an alternative embodiment in which the shocking electrode is positioned into the anterior groove of the right ventricular out-flow tract against the septum (see page 16, lines 29-32).

3. Referring to claims 5 and 26, Heil et al. teach that the pacing/sensing electrode can be implanted along the septal wall of the right ventricle, and depending upon the length of the first defibrillation coil electrode, a portion of the electrode extends along the endocardial wall of the right ventricle (see page 11, lines 10-21 and figure 5). While Heil et al. do not teach explicitly that the fixation element couples the lead to the endocardial surface along a right ventricular outflow tract, a defibrillation electrode length, distance to between the electrode and tip, and distance between the defibrillation electrode and the sensing electrode such that the maximum lengths would cause the fixation element to be placed along a right ventricular outflow tract. With reference to claims 6-7 and 9-10, Heil et al. do not teach the specific ranges taught by the Applicant. However, Heil et al. do teach a range of 1-10 centimeters (see page 4, lines 14-17). Regarding claim 12, Heil et al. teach a second defibrillation electrode that is positioned within a right atrial chamber or a major vein leading to the right atrial chamber of the heart (see page 4, lines 8-16).

4. With regards to claims 13 and 23, the lead is placed such that the sensor would be located below the tricuspid valve (see figures 5 and 12). Regarding claims 14 and 24, Heil et al. teach positioning the lead in various ways against the septal wall that contains the ventricular out-flow tract (see page 16, lines 29-32). Referring to claims

15-18, Heil et al. teach a preformed bend between the sensor and the defibrillation electrode and tip that enables the sensor to be placed against the septal wall and the defibrillation electrode to be placed along the ventricular apex and a right ventricular lateral wall (see figure 5 and page 11, lines 10-21 and lines 32-33 and page 12, lines 1-5). With reference to claims 19 and 20, Heil et al. teach a tubing that protects the lead and sensors (see page 13, lines 4-10 and page 21, lines 7-12 and figures 6A and 8). Regarding claim 29, the positioning of the lead taught by Heil et al. comprises advancing the distal tip toward the apex, withdrawing a stylet, and pushing the lead body into the ventricle (see page 25, lines 3-18). While Heil et al. do not teach explicitly using the stylus to position and shape the lead as claimed in claim 29, Heil et al. do teach using the stylus to position and shape and teach the positioning and shaping of the lead as claimed by the Applicant. Therefore, it is inherent that the stylus would position and shape the lead in the manner as described by the Applicant and Heil et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heil et al. Heil et al. discloses the claimed invention except for the range of approximately 10 cm to approximately 12 cm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a range of the sensor from the distal end being approximately 10 cm to approximately 12 cm. Since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. See In re Aller, 105 USPQ 233 and MPEP 2144.05.

6. Regarding claim 11, Heil et al. teach the device and method described above, but do not teach an electrode pair on the distal tip that contains an electrode that contains an anode and cathode. Heil et al. do teach that the prior art discloses an endocardial lead that features a porous tip electrode which is a tripolar, tined, endocardial lead with a porous tip electrode that serves as the cathode for intracardiac right ventricular electrogram rate sensing and pacing and has a distal electrode serving as the anode (see page 2, lines 24-32). Heil et al. teach that using such a lead is the easiest and most convenient way to perform the implantation of a fully transvenous system (see page 2, lines 22-24). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to combine the lead taught by Heil et al.

with the anode and cathode electrode pair because using such an electrode pair is the easiest and most convenient way to perform the implantation of a fully transvenous system.

7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heil et al. in view of Ferek-Petric (U.S. 5271392). Heil et al. teach the lead described above, but do not teach using polyurethane for the lead body. Ferek-Petric does teach using polyurethane because it is an insulative material and biocompatible (see column 8, lines 4-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the lead disclosed by Heil et al. with the lead body constructed of polyurethane because it is insulative and biocompatible.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 5545205 to Schulte et al. discloses a catheter with distal and proximal electrodes that are effected through the interventricular septum and left ventricular free wall.

U.S. 6505082 to Scheiner et al. discloses a lead that contains to electrodes and a curved portion to facilitate the positioning of the two electrodes.

U.S. 6201994 to Warman et al. discloses a lead for pacing the atria that has an electrode locatable in the right ventricle, and the lead can be pre-formed with laterally extending curves.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephanie Smith 3/20/06
SRS

GEORGE R. EVANISKO
PRIMARY EXAMINER

3/20/6